



PATENT  
Our Docket: P31 8756

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: )  
Richard H. Tullis )  
Serial No.: 07/633,452 )  
Filed: December 20, 1990 )  
For: OLIGONUCLEOTIDE THERAPEUTIC )  
AGENT AND METHODS OF MAKING )  
SAME )

RECEIVED GROUP 18C  
JUL 23 1991  
Group Art Unit: 184

Examiner: Unknown

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on 7/11/91  
Date

By Theresa A. Brown  
Theresa A. Brown, Reg. No. 32,547

July 11, 1991  
Date of Signature

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

DECLARATION IN SUPPORT OF THE PETITION TO  
MAKE APPLICATION RELATING TO BIOTECHNOLOGY SPECIAL

BEST AVAILABLE COPY

Sir:

I, Jerry L. Ruth, declare as follows:

1. I am the Vice President of Molecular Biosystems, Inc. (hereinafter referred to as MBI), a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 10030 Barnes Canyon Road, San Diego, California 92120. I make this declaration in support of the Petition to Make Special in the above-identified biotechnology patent application.

2. MBI is the assignee of the above-identified patent application by virtue of an assignment document executed by the inventor on October 9, 1981, and recorded in the U.S. Patent and Trademark Office on October 23, 1981 (Reel: 3941, Frame: 0775).

3. On December 20, 1990, Vincent Frank, President of MBI, executed a Verified Statement Claiming Small Entity Status pursuant to 37 C.F.R. 1.9(f) and 1.27(c) on behalf of MBI. It is my understanding that the Statement Claiming Small Entity Status was filed in the United States Patent and Trademark Office on December 20, 1990, simultaneously with the filing of the above-identified application. Small entity status has therefore been previously established in connection with the above-identified patent application.

4. The subject matter of the above-identified patent application is a major asset to MBI.

5. MBI is a company devoted to the research and development of oligonucleotides for commercial and research purposes. The above-identified patent application is directed to oligonucleotide therapeutic agents that are suitable for use in a wide variety of biomedical applications, including the control of various biological functions in an organism. The claims in the present application are directed to different aspects of the same subject matter of a related application, which recently issued as U.S. Patent No. 5,023,243 on June 11, 1991.

6. The application is further directed to methods for the systematic design of new therapeutic agents that are versatile and inexpensive, yet extremely specific and effective. Prior to the present invention, it was known that certain therapeutic agents are useful at the onset, but over time many organisms become resistant or totally immune to the agent's action.

7. The technology is currently in high demand. Thus, the development and possible licensing opportunities to

DEPT AVAILABLE COPY

develop the subject matter of the presently claimed invention will be significantly impaired if the examination of the patent application is delayed.

8. Thus far, the development of the oligonucleotide therapeutic agents has proceeded on a relatively small scale. However, in view of the advantages of the oligonucleotide therapeutic agents over known antibiotics and other therapeutic agents, MBI believes that there is a substantial market for the oligonucleotides, both in the United States and abroad.

9. In order to justify the substantial capital expenditures that will be involved in the further development and commercialization of the oligonucleotide therapeutic agents of the present application, it is imperative that MBI be apprised, as early as possible, of the patentability of the presently claimed agents and methods of making them.

I further state that the above statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that any willful false statements may jeopardize the validity of this application and any patent issuing therefrom.

8 July 1991  
Date

Jerry L. Ruth  
Jerry L. Ruth, Ph.D.

BEST AVAILABLE COPY